IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	)	Case No. 08 C 7231
Plaintiffs,	)	Consolidated for all purposes with Case No. 09-cv-6053
v.	)	
APOTEX INC., and APOTEX CORP.,	)	Judge Robert M. Dow, Jr.
Defendants.	)	Magistrate Judge Martin C. Ashman

PLAINTIFF PFIZER'S MEMORANDUM IN OPPOSITION TO APOTEX INC. AND APOTEX CORP.'S MOTION TO COMPEL DISCOVERY

John S. Mortimer
Jeffrey M. Drake
WOOD PHILLIPS
500 West Madison Street
Suite 3800
Chicago, IL 60661-2562
(312) 876-1800

OF COUNSEL:
Rudolf E. Hutz
Jeffrey B. Bove
Mary W. Bourke
Daniel C. Mulveny
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
Wilmington, DE 19899
(302) 658-9141

William E. McShane
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 572-0335

Attorneys for Plaintiffs
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I. INTRODUCTION

Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex" or "Defendants") have moved to compel certain discovery from Plaintiffs (collectively "Pfizer" or "Plaintiffs"). (*See* D.I. 146, Apotex's "Motion to Compel" and D.I. 148, Apotex's "OpenMemo"). Apotex's Motion to Compel demands: (1) documents comprising highly-confidential settlement agreements between Pfizer and three direct competitors of Apotex (collectively the "Settlement Agreement Documents"); and (2) highly-sensitive documents relating to Pfizer's future strategic plans, life-cycle plans, market share projections, and other documents reflecting any anticipated reaction by Pfizer to events that have not yet occurred, namely the entry into the market of generic competition to Pfizer's and the world's most successful pharmaceutical product, ever, called Lipitor® (collectively the "Generic Entry Documents").

Pfizer opposes Apotex's Motion to Compel because Apotex has not met its burden to establish that the demanded discovery is of sufficient relevance to this litigation to warrant the production of highly sensitive corporate information of both Pfizer and of Apotex's generic competitors that would create irrevocable harm to Pfizer (and Apotex's generic competition) if the information was misused by Apotex, whether intentionally or by accident.

II. FACTUAL BACKGROUND

A. The Parties

Pfizer is a research-based global pharmaceutical company, and an innovator and leader in the medical industry. Each year Pfizer invests heavily in research and development to discover, develop, and bring to market new drugs that address major unmet health care needs. Apotex manufactures and sells generic pharmaceutical products that basically copy successful drugs that have been discovered and marketed by others. As a generic manufacturer, Apotex relies on the

innovator's safety and efficacy data, when seeking approval to market copies of another's drug. Generic drug companies like Apotex typically obtain market approval through Abbreviated New Drug Applications ("ANDAs") under the Hatch-Waxman Act.[1]

B. Lipitor®

Lipitor® is Pfizer's brand name for a medication containing atorvastatin calcium as its active ingredient. Lipitor® is used to treat cardiovascular disease and prevent hyper-cholesterolemia thereby preventing heart attacks and stroke. Pfizer's Lipitor® was approved by the FDA in 1996 and sales began in the U.S. in 1997. For many years, Lipitor® has been the most successful pharmaceutical in the world, with annual sales of over ten billion dollars worldwide. Pfizer owns a number of patents that protect Lipitor®, its formulations, its uses and procedures for making it, including U.S. Reissue Patent No. Re 40,667 (the "RE'667 patent"), the patent mainly at issue in Apotex's Motion to Compel.

C. Prior Lipitor® ANDA Litigations with Ranbaxy, Teva, and Cobalt

1. Ranbaxy's ANDA and Worldwide Settlement

Apotex is not the first, or the last, generic company to attempt to copy Lipitor® before Pfizer's relevant patents expire. Indeed, Apotex is the fourth ANDA filer and has been followed by at least four others, all of whom were sued by Pfizer.[2]

On or about August 19, 2002, Ranbaxy filed the first ANDA seeking to market a generic atorvastatin calcium product. Ranbaxy's ANDA attacked all of Pfizer's relevant patents listed in FDA's Orange Book. (*See* Mulveny Decl. Ex A for an explanation of the Orange Book). Pfizer

[1] Attached as Exhibit A to the supporting Declaration of Daniel C. Mulveny ("Mulveny Decl.") is a brief discussion of this Act and its procedures. A more detailed explanation can be found in Judge Dow's Memorandum Opinion and Order in D.I. 144.

[2] Currently, the following active litigations are pending involving Pfizer patents claiming atorvastatin calcium, its use in medicine and/or methods of making it: *Pfizer v. Mylan* (Lipitor®), C.A. No. 09-441 (D. Del.), *Pfizer v. Mylan* (Caduet®), C.A. No. 10-85 (D. Del.), *Pfizer v. Sandoz*, CA No. 09-742 (D. Del.), *Pfizer v. Sandoz*, C.A. No. 10-103 (D. Del.), *Sandoz v. Pfizer*, C.A. No. 10-104 (D. Del.), *Pfizer v Dr. Reddy's Laboratories*, C.A. No. 09-943 (D.Del.), *Pfizer v. Kremers*, C.A. No. 09-924 (D. Del.)

sued Ranbaxy in the Delaware District Court alleging infringement of only two patents, the '893 and the '995 patents. The District Court found both patents valid and infringed, but on appeal the Federal Circuit found a technical defect in the sole asserted '995 claim. *See Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 405 F. Supp. 2d 495 (D. Del. 2005), *affirmed in part*, 457 F.3d 1284 (Fed. Cir. 2006).[3]

Ranbaxy also filed a later ANDA, this time seeking FDA approval to market a generic copy of another Pfizer drug called Caduet®. Caduet® is a unique product that, in a single tablet, contains various ratios of two active ingredients: (1) the same atorvastatin calcium as found in Lipitor® and (2) another active ingredient called amlodipine besylate. Caduet® is used for the treatment of, *inter alia*, hypertension (high blood pressure) and hyperlipidemia (high cholesterol).

As noted above, Pfizer owned patents that cover both Caduet®'s active atorvastatin calcium ingredient (including the '995 patent and now its RE'667 reissue) as well as the use of Caduet® to treat hypertension and hyperlipidemia (the '574 patent expiring in 2018). Pfizer therefore filed a separate lawsuit against Ranbaxy due to this Caduet® ANDA.

On June 18, 2008, Pfizer and Ranbaxy announced a worldwide settlement of their various patent disputes, including those involving Lipitor® and Caduet®. Ranbaxy was granted a license to sell generic versions of Lipitor® and Caduet® under all relevant Pfizer United States patents effective November 30, 2011. (*See* Mulveny Decl. Ex. B). The detailed terms and conditions of the Ranbaxy settlement have remained confidential to the parties to the settlement.

[3] Pfizer cured this technical defect by the reissue procedure set forth in 35 U.S.C. § 251. The U.S. Patent and Trademark Office ("USPTO") granted a reissue patent, RE'667, based on the '995 patent containing the corrected claim.

2. The Teva and Cobalt Litigations and Settlements

Teva Pharmaceuticals USA Inc. and Cobalt Pharmaceuticals, Inc. each also filed for approval to market generic versions of Lipitor®. Pfizer therefore sued both companies for infringement of, *inter alia*, the '995 patent. *See Pfizer Inc. v. Teva Pharms. USA Inc.*, C.A. No. 07-360-JJF (D. Del. 2007); *see also Pfizer Inc. v. Teva Pharms. USA Inc.*, C.A. No. 08-237-JJF (D. Del. 2007); *Pfizer Inc. v. Cobalt Pharms., Inc.*, C.A. No. 07-790-JJF (D. Del. 2008).[4] Teva and Cobalt separately reached settlements with Pfizer. The detailed terms of these settlements have remained confidential to each of the parties to the respective settlements.

3. Apotex's ANDA

Apotex sat back awaiting the outcomes of these suits. As the fourth ANDA filer for generic Lipitor®, Apotex belatedly filed its ANDA more than six years after Ranbaxy. In response, Pfizer initiated this action alleging, *inter alia*, that Apotex's ANDA infringed Pfizer's '995 and RE'667 patents.

D. Apotex Demands Discovery of Pfizer's Settlement Agreement Documents and Generic Entry Documents

Pfizer and Apotex exchanged discovery demands in this litigation. The instant dispute arises from Apotex's insistence that Pfizer must produce the Settlement Agreement Documents and its Generic Entry Documents. The dispute centers on certain (but clearly not all) documents within Apotex's Request for Documents Nos. 114-15 and 122-23, reproduced in Apotex's OpenMemo, p. 4. Pfizer's objections to these requests are found in Alul Ex. D (D.I. 149-4), pp. 77-78 and 81-82, as further explained in Alul Ex. F (D.I. 149-6), p. 25. These objections include objections based on the attorney-client privilege and work-product exceptions which, contrary to Apotex's suggestions (OpenMemo, p. 6 and 13), have not been waived and remain applicable.

[4] All unpublished opinions cited herein are attached in alphabetical order as Exhibit 1.

III. ARGUMENT

The Court should not allow Apotex to proceed with its fishing expedition. While the Federal Rules allow broad discovery, discovery is not unlimited. *Hickman v. Taylor*, 329 U.S. 495, 507 (1947). Matters not "reasonably calculated to lead to the discovery of admissible evidence" are outside the scope of the Rules. Fed. R. Civ. P. 26(b)(1). Here, the documents demanded are highly confidential on their face and Apotex has not made a sufficient showing that access to Pfizer's Settlement Agreement Documents and Generic Entry Documents will lead to the discovery of admissible evidence.

A. Apotex has failed to establish that production of the highly-confidential Settlement Agreement Documents to a direct competitor will lead to the generation of admissible evidence

Apotex's demand for the Settlement Agreement Documents fails for three reasons.

1. The Settlement Agreement Documents are not relevant to any issue in this case

First, Apotex's demand for the Settlement Agreements between Pfizer and other generic drug companies, each being potential direct competitors with Apotex, is based upon pure speculation that the settlements are somehow relevant to this litigation. Apotex claims that the agreements are relevant to secondary considerations of nonobviousness because Pfizer may rely on licensing of the RE'667 patent as a secondary consideration. (OpenMemo at 7). Pfizer, however, has never alleged that it will rely upon this licensing. (*See* Pfizer Resp. to Apotex Interrog. No. 6 [Alul Decl. Ex. H, (D.I. 149-8)], and Alul Decl. Ex. F (D.I. 149-6), pp. 1-4, 13 and 18-21 describing Pfizer's reliance—and supporting evidence—on the commercial and medical success of Lipitor®, not licensing).

Instead, if secondary considerations of nonobvious are even necessary, which Apotex has yet to establish, Pfizer has clearly stated that it intends to rely on the widely established

commercial success of Lipitor® which has been and continues to be the world's most successful drug with annual sales in many years of well over $10 billion worldwide. *Id.* Further, if necessary, Pfizer will show that Lipitor® was launched into a market already populated by other drugs of the same general class (called statins) yet Lipitor® came to dominate the market due to the superior efficacy of atorvastatin calcium compared with the existing statins marketed at the time. *Id.*

In fact, Pfizer has already established the commercial and medical success of Lipitor® at trial in *Pfizer v. Ranbaxy*, No. 03-209-JJF (D. Del.). *See Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 405 F. Supp. 2d at 518. Apparently, Apotex nonetheless intends to relitigate the commercial and medical success of Lipitor®. But Apotex cannot use this quixotic endeavor to pry into highly-confidential settlement agreements with its competitors. To emphasize again, Pfizer is not relying and will not rely on any licensing of the RE'667 patent including settlement agreements with Ranbaxy, Cobalt, and/or Teva or otherwise,[5] and, therefore, the Settlement Agreement Documents are outside the bounds of proper discovery.

2. In addition to being irrelevant, the Settlement Agreement Documents are protected by the settlement privilege

(a) The settlement privilege preserves the judicial efficiency that comes with settlements

Second, the Settlement Agreement Documents are protected by the "settlement privilege". This privilege has been recognized by the courts as necessary to protect the settlement process. The Sixth Circuit has noted that the settlement privilege arises out of Federal Rule of Evidence 501 which authorizes the federal courts to determine new privileges by

[5] *American Standard, Inc. v. Pfizer, Inc.*, cited in Apotex's OpenMemo, pp. 8-9, 13, is distinguishable from the present case. In *American Standard*, the patent holder stated to the alleged infringing party that it intended to rely on a third-party settlement agreement at trial. *Am. Standard, Inc. v. Pfizer, Inc.*, MISC. 87-1-73-IP, 1988 WL 156152, at *2 (S.D. Ind. July 8, 1988).

examining "principles of the common law...in the light of reason and experience." *Goodyear Tire & Rubber Co. v. Chiles Power Supply, Inc.*, 332 F.3d 976, 979-80 (6th Cir. 2003). The Court reasoned that there is "a strong public interest in favor of secrecy of matters discussed by parties during settlement negotiations." *Id.* at 980. The Court further found that the "ability to negotiate and settle a case without trial fosters a more efficient, more cost-effective, and significantly less burdened judicial system." *Id.* "In order for settlement talks to be effective," the Court concluded that "parties must feel uninhibited in their communications." *Id.* "Without a privilege," the Court worried that "parties would more often forego negotiations for the relative formality of trial." *Id.* This would lead to the collapse of the entire negotiation process and with it, the judicial efficiency that comes from settlement. *Id.*

The Northern District of Illinois has acknowledged the settlement privilege stating that: "Several courts have concluded that there is a settlement privilege, and that statements made in the context of private or court sponsored settlements or mediations are immune from discovery, at least discovery from third parties." *Steele v. Lincoln Fin. Group*, No. 05-C-7163, 2007 WL 1052495, at * 4 (N.D. Ill. Apr. 3, 2007) (citing *Stockman v. Oakcrest Dental Ctr. P.C.*, 480 F.3d 791, 797-98 (6th Cir. 2007)). In *Steele*, the Court did not invoke the privilege, instead finding that counsel for the parties inadequately briefed the Court on the issue. *Steele*, 2007 WL 1052495, at *4 n.2 (noting that "the parties' briefs effectively provide no guidance, and thus any ruling on the issue would be far less informed than it should be.").[6]

Moreover, this Court has found that "[t]he policy favoring freely-negotiated settlements is one of the strongest in the federal courts." *Vardon Golf Co. v. BBMG Golf Ltd.*, 156 F.R.D. 641, 652 (N.D. Ill. 1994). The Settlement Agreement Documents at issue here were entered into

[6] Of course, this Court can dispose of Apotex's Motion without reaching the settlement privilege issue simply on the basis of lack of relevancy.

with the express provision that the agreement terms will remain confidential. In the many Lipitor® and Caduet® litigations Pfizer has initiated, Pfizer has consistently maintained the confidentiality of these third-party Settlement Agreement Documents and has never produced them to anyone.

Accordingly, this Court should find that Pfizer's Settlement Agreement Documents are protected by a settlement privilege because (1) there exists a strong public policy in support of promoting the settlement of cases and, thereby, judicial efficiency; and (2) the"'[s]ecrecy of settlement terms...is a well-established American litigation practice.'" *Goodyear*, 332 F.3d at 980-81 (quoting *Palmieri v. New York*, 779 F.2d 861, 865 (2d Cir. 1985)). To find otherwise under the circumstances of this case would set a chilling precedent for future settlements because parties will not wish to enter into settlements for fear that a competitor seeking discovery in a subsequent litigation will obtain the settlement agreements through discovery and use the contents of the settlement agreement against them. *See Vardon*, 156 F.R.D. at 652 ("[a]llowing discovery regarding the negotiations between parties to ongoing litigation could very easily have a chilling effect on the parties' willingness to enter into settlement negotiations"). In this case, the policy of encouraging settlements taken with the lack of probative value of the Settlement Agreement Documents counsels denial of Apotex's demands.

(b) Apotex incorrectly states that there is no settlement privilege

Apotex's argument that the Courts have "uniformly rejected" the assertion of the settlement privilege is wrong. (*See* OpenMemo at 11). The Seventh Circuit did not clearly reject the existence of the settlement privilege in *In re General Motors Corp. Engine Interchange Litigation*, 594 F.2d 1106, 1124 n.20 (7th Cir. 1979), as Apotex contends. Rather, the *General Motors* Court first noted that the parties did not brief the issue and then the Court explained that in the context of a class action settlement, Rule 23(e) requires approval of the settlement by the

trial court. *General Motors*, 594 F.2d at 1124 n.20. In such circumstances, the Court noted that the parties should expect judicial review of any settlement. Thus, *General Motors* is not dispositive as to whether the settlement privilege exists.

3. Apotex has failed to make the required showing that the balance of interests tips in favor of the production of Pfizer's Settlement Agreement Documents

Last, the Northern District of Illinois District Court held that "a court should engage in a balancing of interests between Rule 26(b)(1)'s liberal scope of permissible discovery and the policy desire of attempting to prevent the chilling of settlement negotiations." *Clark v. Experian Info. Solutions, Inc.*, No. 03-7882, 2006 WL 931677, at *4 (N.D. Ill. Apr. 10, 2006). Here, Apotex has failed to show the balance of interest tips in its favor. Apotex spends pages speculating as to possible reasons why the Settlement Agreement Documents might be relevant based on facts of its own manufacture and not actually present in the current litigation. For the following four reasons, Apotex's speculations fail to outweigh the important public policy of encouraging settlement negotiations.

(a) Pfizer will not rely on licensing of the RE'667 patent as a secondary consideration of nonobviousness

First, as detailed above, Pfizer will not rely on the licensing of the RE'667 (or any other) patent as a secondary consideration of nonobviousness for that patent. Thus, the Settlement Agreement Documents are irrelevant to Apotex's obviousness defense and Pfizer's rebuttal thereof.

(b) Apotex's patent misuse defense is purely speculative

Second, Apotex's newly minted "patent misuse" defense is nonsensical at best. Apotex has never even pleaded misuse as an affirmative defense. Regardless, it is fanciful to believe that Pfizer, or any other company, would risk losing a multibillion-dollar franchise like Lipitor®,

which is protected by the RE'667 patent, by misusing the patent in settlements with other generic drug companies. And this is especially true given that by law the settlement agreements at issue had to be submitted for review to both the Federal Trade Commission and the U.S. Department of Justice. (Mulveny Decl., Ex C).

Apotex's Memorandum openly wonders why Ranbaxy agreed not to enter the market until November 30, 2011, which is after the expiration of the RE'667 patent. (OpenMemo at 2).[7] Apotex suggests that this later date is *per se* patent misuse and therefore it should be entitled to discover Pfizer's Settlement Agreement Documents to satisfy its curiosity as to Ranbaxy's motivation to settle the Lipitor® and Caduet® disputes. *Id.*

Apotex's curiosity, however, is not the foundation of a patent misuse defense even if misuse were properly raised by the pleadings, which Apotex has not. And Apotex's curiosity is readily cured by Ranbaxy's own press release regarding the settlement which explains that the settlement involved multiple unrelated products (*e.g.,* Accupril) and multiple patent disputes worldwide. (*See* Mulveny Decl. Ex. B). Moreover, Ranbaxy negotiated a license to sell generic Lipitor® and Caduet® products before the expiration of several other Pfizer atorvastatin patents. *Id*. Ranbaxy identifies these patents as the basic compound patent (*i.e.,* '893), the enantiomer patent (*i.e.,* '995 and RE'667), various process and crystalline form patents (*e.g.,* '156), and the combination of atorvastatin calcium and amlodipine besylate patent (the '574 patent which covers the use of Caduet®). As the release plainly states, the patents involved in the settlement with Ranbaxy have patent terms that extend to 2016, 2017, and 2018, well beyond the November 30, 2011 date complained of by Apotex. *Id.*

[7] To pretend a significant delay, Apotex asserts that a different patent, the '893 patent, expired on March 24, 2010 and thus Ranbaxy agreed to "delay" marketing for over 20 months. (OpenMemo at 2). This ignores other, relevant Pfizer patents with longer expiration dates, including the '995 and RE'667 patents providing exclusivity (including pediatric exclusivity) until December 28, 2010.

In fact, publicly available consent orders in the Pfizer-Ranbaxy litigations establish that Ranbaxy was enjoined until November 30, 2011 from infringing several atorvastatin calcium patents which did not expire until well after that date. (Mulveny Decl., Exs. D-F).

Thus, even a cursory review of Ranbaxy's press release and publicly available documents from the courts eliminates Apotex's worries about why Ranbaxy was willing to stay off the market until November 30, 2011, assuming such concerns could be a proper basis for this discovery (which they are not). Among other things, Ranbaxy obtained patent clearance by settlement for all of Pfizer's atorvastatin patents well-before expiration dates of 2016, 2017, and 2018. Thus, the "delay", if there indeed is any delay, in Ranbaxy generic Lipitor® launch to November 2011 cannot be *per se* evidence or even a suggestion of patent misuse as Apotex contends. In sum, Apotex is speculating with its non-plead patent misuse defense, and speculation is not a proper basis to discover the highly confidential Settlement Agreement Documents involving Apotex's competitors.

(c) Discovery of Pfizer's Settlement Agreement Documents would unfairly provide Apotex and its attorneys important business information of Apotex's generic competitors

Third, the Settlement Agreement Documents involve several of Apotex's closest competitors. Production of these agreements—which are highly confidential to Pfizer and these generic companies—gives Apotex and its litigation counsel inside knowledge about Apotex's closest competitors' generic Lipitor® plans. No such competitive advantage over competitors through these highly-sensitive Settlement Agreement Documents should be allowed based on nothing more than speculation, even if in theory they are placed under a protective order. The existence of a protective order does not eliminate the requirement that the information sought must be relevant. *See, e.g., In re Wells Fargo Residential Mortgage Lending Discrimination*

Litig., No. C-08-1030, 2009 WL 1771368 (N.D. Cal. June 19, 2009), at *6; *Datacom Sys., Inc. v. JDL Digital Sys., Inc.*, No. 6:08-cv-06102, 2009 WL 3837213, at *3 (W.D. Ark. Nov. 13, 2009).

(d) The Settlement Agreement Documents are moot with regards to Pfizer's, now-decided, motion to dismiss Apotex's counterclaims

Fourth, Apotex's argument that the Settlement Agreement Documents are relevant to Pfizer's motion to dismiss (D.I. 113) is moot by reason of the Court's June 30, 2010 decision to deny Pfizer's motion to dismiss. (D.I. 144). Although Pfizer has sought reconsideration of this decision, reconsideration is based solely on a very narrow issue regarding Apotex's defective Offer of Confidential Access, an issue having nothing to do with Apotex's speculative theories for the relevancy of the instant discovery. (*See* Mulveny Decl., Ex. G).

B. The Generic Entry documents are similarly irrelevant and beyond the scope of discovery

Apotex makes two arguments why it is entitled to discover Pfizer's future business plans after the launch of a generic Lipitor® product: (1) the Generic Entry Documents are relevant to the issue of commercial success; and (2) the Generic Entry Documents are relevant to whether Pfizer can show irreparable harm sufficient to warrant a permanent injunction. Both arguments are meritless.

1. The Generic Entry Documents are not relevant to the issue of commercial success

The Generic Entry Documents are irrelevant to commercial success. As Pfizer demonstrated earlier, if necessary to rebut a *prima facie* case of obviousness, Pfizer intends to rely on the <u>past</u> sales of Lipitor® as well as the <u>already</u> <u>established</u> medical success of Lipitor® (*e.g.*, as already found by the Delaware District Court—see Section III.A.1, *supra*). Pfizer will not rely on the <u>future</u> potential success of Lipitor® once a generic competitor has entered the marketplace. Apotex cannot explain how Pfizer's <u>future</u> business plans <u>after</u> the RE'667 patent

expires somehow relate to the obviousness/nonobviousness of the RE'667 patent before it expires.

2. Pfizer is entitled to an automatic injunction by statute upon a finding of infringement, rendering the Generic Entry Documents irrelevant to the issue of whether an injunction is warranted

Regarding an injunction, Apotex incorrectly argues that 35 U.S.C. § 271(e)(4)(B) controls the analysis whether an injunction is permissive or mandatory. (*See* OpenMemo at 14). Apotex neglects to mention that the corresponding ANDA injunctive relief provision, § 271(e)(4)(A), mandates that the Court automatically enjoin the FDA from approving an ANDA found to infringe a patent under § 271(e)(2) until the expiration of the patent. *See* 35 U.S.C. § 271(e)(4)(A) ("the court shall order the effective date of any approval of the drug...to be a date which is not earlier than the date of the expiration of the patent...") (emphasis added). By law, without FDA approval, an ANDA filer cannot market its ANDA product in the United States.

Read together, 35 U.S.C. §§ 271(e)(4)(A) and (B) effectively award the successful patentee in an ANDA case an automatic permanent injunction that prevents the commercial sale of the ANDA product until after the expiration of the patent(s) in suit.

Further, Apotex's argument that 35 U.S.C. § 271(e)(4)(B) is effectively the same as the general infringement injunctive relief provision, 35 U.S.C. § 283, has been rejected by the Federal Circuit. In modifying an injunction as overbroad, the Federal Circuit found that 35 U.S.C. § 271(e)(4)(B) provides limited injunctive relief for only the approved drug, relief which is more limited in scope than that permitted under 35 U.S.C. § 283. *Forest Labs., Inc. v. Ivax Pharm., Inc.*, 501 F.3d 1263, 1271-72 (Fed. Cir. 2007). The Court found that, while an injunction under § 271(e)(4)(B) may properly extend to the approved drug, "it should not extend to the remainder of the products covered by the patent." *Id.* Thus, it is clear that § 271(e)(4)(B) and § 283 are not the same. Therefore, *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006),

which was limited to § 283 injunctions, does not alter the statutory requirements of § 271(e)(4)(A) and (B) which mandate the award of injunctive relief upon a finding of ANDA infringement. The language of § 271(e)(4) is unambiguous—Congress clearly intended that upon a finding of infringement by an ANDA applicant, the prevailing patentee was to be free from generic competition from the ANDA product until the expiration of the infringed patents.

Accordingly, because Pfizer is entitled by statute to automatic injunctive relief upon a finding of infringement, there is no need for Apotex to obtain Pfizer's Generic Entry Documents as there is no requirement that Pfizer prove irreparable harm upon a finding of infringement to obtain an injunction preventing Apotex's commercial sale of generic Lipitor®.

3. In any event, the Generic Entry Documents are not relevant to irreparable harm assuming irreparable harm need be proven

Understandably, Apotex as a generic competitor wants Pfizer's highly-confidential business plans and strategies created to combat generic competition once the RE'667 patent expires. However, as of the expiration date of this patent, no injunction could issue and thus there would be no need to establish irreparable harm even if it were an otherwise relevant factor. Under Apotex's theory, Pfizer would be required to prove irreparable harm for an injunction issuing before RE'667's expiration, yet the Generic Entry Documents it seeks are focused on business strategies and plans for periods after RE'667's expiration.

Thus, access by direct competitor Apotex to Pfizer's highly-confidential Generic Entry Documents should not be permitted.

IV. CONCLUSION

For all the above reasons, Pfizer respectfully requests that Apotex's Motion to Compel be denied.

RESPECTFULLY SUBMITTED,

/s/Jeffrey M. Drake
John S. Mortimer
Jeffrey M. Drake
jmdrake@woodphillips.com
WOOD PHILLIPS
500 West Madison Street
Suite 3800
Chicago, IL 60661-2562
(312) 876-1800

OF COUNSEL:
Rudolf E. Hutz
Jeffrey B. Bove
Mary W. Bourke
Daniel C. Mulveny
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
Wilmington, DE 19899
(302) 658-9141

William E. McShane
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 572-0335
Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I, Jeffrey M. Drake, caused to be served a copy of the foregoing:

PLAINTIFF PFIZER'S MEMORANDUM IN OPPOSITION TO APOTEX INC. AND APOTEX CORP.'S MOTION TO COMPEL DISCOVERY

by filing same with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following counsel of record:

William A. Rakoczy
Andrew M. Alul
Rakoczy Molino Mazzochi Siwik, LLP
6 West Hubbard Street
Suite 500
Chicago Illinois 60654

Attorneys for Defendants Apotex Inc. and Apotex Corp.

/s/Jeffrey M. Drake